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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,308	01/02/2002	Hugo A.G. Geerts	JAB-1515	8790

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EXAMINER

BERTOGLIO, VALARIE E

ART UNIT PAPER NUMBER

1632

DATE MAILED: 06/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/030,308	Applicant(s) GEERTS ET AL.	
	Examiner Valarie Bertoglio	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 52-65 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 52-65 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01/02/2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicant's amendment filed 03/25/2004 has been entered. Claims 1-51 have been cancelled. Claims 53-65 have been added, are pending and are under consideration in the instant office action.

Drawings

The drawings are objected to because the drawings are not in consecutive order (see 37 CFR 1.84(u)(1)). Figure 14e is presented on drawing sheet 13, whereas Figure 14a is presented on drawing sheet 14. Furthermore, CFR 1.84(u)(2) states that brackets should not be used in identifying views. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

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Claims 56-65 objected to because of the following informalities: Referring to "The" subject of a previous claim, rather than "A", is proper format for a dependent claim.

Accordingly, "A vector" in claims 53-63 should read "The vector"; "a" vector in claim 63 (line 2) should read "the vector" and "A" host cell in claims 64 and 65 should read "The host cell".

Appropriate correction is required.

Claim Rejections - 35 USC § 112-1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 52-65 are rejected under 35 U.S.C. 112, first paragraph for reasons of record as applied to claims 1-11 and 20-23 in the office action of 07/02/2004 at pages 2-8, because the specification, while being enabling for 1) a nucleic acid vector comprising a nucleic acid sequence encoding a human Tau protein operably linked to a sequence that directs expression of said human Tau nucleic acid in the nervous system wherein the sequence directing expression is the Thyl promoter and wherein the vector is capable of integrating into the endogenous Tau equivalent gene of a mouse and for 2) an in vitro isolated, pluripotent or lineage restricted host cell transformed, transfected or injected with a vector comprising a nucleic acid sequence encoding a human Tau protein operably linked to a sequence that directs expression of said human Tau nucleic acid in said cell wherein the sequence directing expression is the Thyl promoter and wherein the vector is capable of integrating into the endogenous Tau equivalent gene, does not reasonably provide enablement for any sequence capable of directing expression of said human Tau nucleic acid in the nervous system or a vector wherein said vector can be

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targeted to the tau gene in the genome of any species of non-human animal, wherein said vector prevents expression of the endogenous Tau equivalent gene or 2) a cell in vivo or any totipotent cell comprising the claimed vector. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicants' arguments have been thoroughly considered and are not fully persuasive.

Applicant argues that specification provides ample guidance to use the claimed nucleic acid with a promoter to drive the expression of human Tau in the nervous system of a mouse (page 4, paragraph 3 of Applicants' remarks). Applicant also argues that there is sufficient guidance to permit one skilled in the art to apply ES cell technology to make and use the non-human mammalian cells encompassed by the claims (page 4, paragraph 4 of Applicants' remarks).

In response, the first grounds of the rejection relates to the breadth of the claims with respect to the promoter used in the claimed nucleic acid. The claims encompass any promoter capable of causing expression in the nervous system. The specification does not provide the guidance necessary to make and use the claimed vectors other than that comprising the Thy1 promoter. As set forth in the previous office action mailed 07/02/2004, it is not predictable what nervous system promoters will make an adequate amount of human Tau such that in conjunction with kinase expression in vivo, the animal will be a model for the study of Alzheimer's disease (see page 4, paragraph 2; paragraph bridging pages 5-6). The specification does not provide the guidance necessary to determine what other promoters encompassed by the claims will result in an animal that will be a model for the study of Alzheimer's disease and the specification fails to set forth any other use for the claimed nucleic acid vector.

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With respect to the second grounds of the rejection, pertaining to newly added claims 52-62 (previously pending claims 1-11), the rejection is based on the breadth of the species of animal encompassed by the claim. Applicant has amended claim 52 to read only on mouse. As such, this aspect of the rejection is withdrawn for claims 52-64. However, the rejection is maintained for reasons of record set forth on pages 6-7 of the office action mailed 07/02/2004 as it relates to claims 63-65 because the scope of these claims is not limited to mouse. Claims 63-65 should be limited to mouse cells or to isolated cells in vitro.

Further aspects of the rejection do not appear to have been addressed directly by Applicant. Claim 52 is rejected for the same grounds that claim 1 was rejected for reasons set forth at page 7, paragraph 2-page 8 paragraph 1 of the office action mailed 07/02/04. Claim 52 is drawn to a nucleic acid vector that merely comprises a nucleic acid sequence encoding Tau and a promoter and the claim does not require operable linkage between the two elements or require that the human Tau gene be expressed. Without operable linkage, the human Tau gene would not be expressed. It would require undue experimentation to determine how to use the claimed nucleic acid vector where when in the genome of a mouse, it is not expressed.

The previous rejection of claim 23 is maintained as it applies to newly added claim 65. The claim is rejected because it reads on totipotent non-mouse ES cells. As set forth in the previous office action, the state of the art was that totipotent ES cells have only been isolated for mouse. Totipotent ES cells have not been isolated from any non-mouse species of mammal (see page 8, paragraph 2 of the office action mailed 07/02/04). Applicant submits that there is sufficient guidance in the specification to apply ES cell technology to make and use the non-human cells encompassed by the claims. In response, it is noted that the rejection is not applied

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to claims 63 and 64 that are drawn to any cell type or any embryonic cell type. The rejection is applied only to claim 65, drawn to ES cells and encompassing all non-human mammalian species of totipotent and pluripotent ES cells. As set forth on pages 7-8 of the office action mailed 02/11/2004, it was well established in the art that totipotent ES cells were not available for any non-mouse species at the time of filing. The specification does not provide any guidance with respect to how to isolate such cells. Therefore, the rejection is maintained.

Claim Rejections - 35 USC § 112-2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 52-65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 52 recites, in step b, "a sequence capable of directing expression of said human Tau protein". This is unclear because genes are expressed, while proteins are the products of gene expression. Furthermore, "capable of directing expression" is a latent property and it is unclear whether expression actually occurs or that the nucleic acid could potentially drive expression upon modification or treatment by certain conditions. "Capable of" implies a latent property and the conditions for the latent property must be clearly defined. Therefore, it is unclear if the latent property is ever obtained. Claims 53-65 depend from claim 52 and are included in this rejection.

The following are new grounds of rejection that are necessitated by amendment.

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Claims 52,56 and 59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 52 recites the limitation "said animal" in line 7. There is insufficient antecedent basis for this limitation in the claim.

Claim 56 recites the limitation "a vector according to claim 4" in line 1. There is insufficient antecedent basis for this limitation in the claim. Claim 4 is a cancelled claim. Based on the previously pending claims, it appears that claim 56 should depend from claim 55 and will be examined accordingly.

Claim 59 recites the limitation "said animal" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

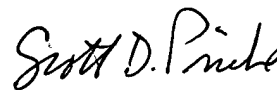
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is (571) 272-0725. The examiner can normally be reached on Mon-Thurs 5:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Valarie Bertoglio
Examiner
Art Unit 1632


SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER